### PATENT COOPERATION TREATY

## **PCT**

REC'D 2 8 JUN 2004

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference Case 21413			ent's file reference	FOR FURTHER A	R ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)			
International application No. PCT/EP 03/10296				International filing date 16.09.2003	(day/mon		Priority date (day/month)	
Inter		al Pat	ent Classification (IPC) or bo		and IPC		27.05.2002	
Applicant DSM IP ASSETS B.V. et al.								
This International preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.								
2.	This REPORT consists of a total of 6 sheets, including this cover sheet.							
	This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).							
	These annexes consist of a total of sheets.							
3.	This	repo	rt contains indications rel	ating to the following i	tems:			
	1	$\boxtimes$	Basis of the opinion					
	11		Priority					
	111		Non-establishment of o	pinion with regard to r	novelty, in	ventive step a	nd industrial applicability	y
	IV		Lack of unity of invention					
	V	☒	Reasoned statement un citations and explanation	nder Rule 66.2(a)(ii) w ons supporting such st	ith regard atement	I to novelty, inv	entive step or industria	l applicability;
	VI		Certain documents cite	d				
	VII		Certain defects in the in					
	VIII		Certain observations or	n the international app	lication			
Date of submission of the demand			Date of	completion of this	s report			
16.10.2003				25.06.2004				
Name	Name and mailing address of the international preliminary examining authority:					ed Officer		has Pelan
European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016					Kamp, M			
					Telepho	ne No. +31 70 34	10-2373	Sandana onpio office

l. Basis	of the	report
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 With regard to the elements of the international application (Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)):

	0	Description, Pages							
	1	-12	as originally filed						
	C	laims, Numbers							
	1-	-7	as originally filed						
	Drawings, Sheets								
	1/	1	as originally filed						
Sequence listing part of the description, pages:									
	1, as originally filed								
			guage, all the elements marked above were available or furnished to this Authority in the international application was filed, unless otherwise indicated under this item.						
	Th	ese elements were a	available or furnished to this Authority in the following language: , which is:						
		the language of a translation furnished for the purposes of the international search (upd. 18.1).							
		and a publication of the international application (under Rule 49 9/h)							
		the language of a t Rule 55.2 and/or 5	ranslation furnished for the purposes of international preliminary examination (under 5.3).						
<ol> <li>With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:</li> </ol>									
į	X	contained in the international application in written form.							
[	Ø	filed together with the international application in computer readable form.							
_	]	nurnished subsequently to this Authority in written form.							
	]	furnished subsequently to this Authority in computer readable form							
	]	I he statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.							
Ε	]	The statement that the listing has been furn	the information recorded in computer readable form is identical to the written sequence ished.						
4. T	4. The amendments have resulted in the cancellation of:								
		the description,	pages:						
	)	the claims,	Nos.:						
	] -	the drawings,	sheets:						

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP 03/10296

5. 🗆	This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).
	(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N) Yes: Claims 1-7

No: Claims

Inventive step (IS) Yes: Claims 1-7

No: Claims

Industrial applicability (IA) Yes: Claims 1-7

No: Claims

2. Citations and explanations

see separate sheet

**EXAMINATION REPORT - SEPARATE SHEET** 

The examination is being carried out on the following application documents:

Text for the Contracting States:

AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IT LI LT LU LV MC MK NL PL PT RO SE SI SK TR

Description, pages:

1-12

as originally filed

Claims, No.:

1-7

as originally filed

Drawings, sheets:

1/1

as originally filed

Sequence Listing, pages:

1

as originally filed

#### 2.1 CITATIONS

Reference is made to the following document:

D1: TAZOE M ET AL: 'Production of vitamin B6 in Rhizobium', BIOSCIENCE BIOTECHNOLOGY BIOCHEMISTRY, vol. 63, no. 8, August 1999 (1999-08), pages 1378-1382

#### 2.2 NOVELTY (Art. 33(2) PCT)

2.2.1 D1 is regarded as being the most relevant state of the art with respect to the subject-matter of independent claims 1 and 6, disclosing a microorganism of the genus Sinorhizobium (or Rhizobium) which produces vitamin B6, in particular S. meliloti IFO 14782, as well as its use in a process for producing vitamin B6. The subject-matter of claims 1 and 6 differs from D1 in that a

mutant of said strain is claimed having a recombinant plasmid harbouring the pyridoxol 5'-phosphate synthase-encoding pdxJ gene, and which mutant strain has acquired histidine requirement and/or glycine resistance.

Hence, the present application satisfies the criterion set forth in Article 33(2) 2.2.2 PCT because the subject-matter of claims 1-7 is new in respect of the prior art as defined in the regulations (Rule 64(1)-(3) PCT), particularly in view of D1.

#### 2.3 INVENTIVE STEP (Art. 33(3) PCT)

- 2.3.1 Document D1 is also considered to represent the closest prior art with respect to evaluating inventive step of claims 1 and 6.
- The problem to be solved by the subject matter of claims 1 and 6 is to 2.3.2 provide microorganisms and processes for improved production of vitamin B6. The solution would be a mutant of a recombinant strain of the genus Sinorhizobium having a plasmid containing a pdxJ gene (encoding pyridoxine 5'-phosphate synthase), said mutant strain having acquired histidine requirement and/or glycine resistance, as well as a process for producing vitamin B6 comprising cultivating said strain, with the effect of increasing the production of vitamin B6 (cf. Table 1 on page 12 of the description).
- 2.3.3 This solution can be considered as involving an inventive step (Article 33(3) PCT) for the reason that, although D1 states that Sinorhizobium meliloti IFO 14782 as highest vitamin B6 producer amongst a number of tested strains would be good starting material for further improvement of its vitamin productivity by classical mutagenesis as well as genetic engineering in the future (cf. D1 page 1381 right-hand column line 21-26), no incentive is given (neither in D1 or in any other document found in the prior art) as to what or which mutations, effected either via genetic engineering and classical mutagenesis, should or would result in higher vitamin B6 production.
- 2.3.4 The present application does therefore satisfy the criterion set forth in Article 33(3) PCT and the subject-matter of claims 1-7 does involve an inventive

step (Rule 65(1)(2) PCT).

## 2.4 INDUSTRIAL APPLICABILITY (Art. 33(4) PCT)

2.4.1 The subject-matter of **claims 1-7** satisfies the criterion set forth in Art. 33(4) PCT in conjunction with Rule 5(vi) PCT with respect to industrial applicability.